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SUMMMARY OF SAFETY AND EFFECTIVENESS

Applicant or Sponsor:

Biomet Orthopedics, Inc.
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587

Contact Person:

Sara B. Shultz
Biomet Orthopedics, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587
Phone: (219) 267-6639
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Proprietary Name: Self-Countersinking Bone Screw

Common or Usual Name: bone screw

Classification Name: Screw, Fixation, Bone (888.3040)

Device Product Code: 87HWC

Substantially Equivalent Devices: Synthes 3.0mm Cannulated Screw and Threaded Washer, K962823, Synthes (USA), Synthes 3.5mm and 4.0mm Cannulated Screws, K963192, Synthes (USA), DePuy-Ace 4.0mm Cannulated Cancellous Screw, 510(k) unknown, Alphatec 2.7mm (K923256), 3.5mm (K922332), and 4.0mm (510(k) unknown) Cortical Lag Screw, Alphatec Mfg, Inc.

Indications for Use: The Self-Countersinking Bone Screw is indicated for the following conditions:

- Fixation of fractures in long bones such as the fibula, tibia, humerus, radius and ulna as well as fractures in the patella
- Fixation of small bones such as those in the foot, ankle, wrist, and elbow
- Ligament reconstruction
- Arthrodesis of the foot, ankle, wrist, and elbow
- Small bone osteotomies
- Osteochondritis dissecans

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Device Description: The Self-Countersinking Bone Screw is a titanium screw that has cutting flutes in its head that allows it to cut into the bone, thus countersinking itself. The screw is also cannulated to allow insertion over a guide wire. The threads are self-drilling and self-tapping.

The screw will be available with diameters of 2.7mm and 4.3mm. The 2.7mm screws will have lengths from 8mm to 16mm (in 1mm increments) and 18mm to 36mm (in 2mm increments). All lengths of the 2.7mm screw are available fully threaded, with a short partial thread of 1/3 screw length and with a long partial thread of 1/2 screw length. The 2.7mm screw has a cannulation that will accept a 1.1mm guide wire.

The 4.3mm screw will have lengths from 10mm to 36mm (in 2mm increments) available fully threaded, with a short partial thread of 1/3 screw length and with a long partial thread of 1/2 screw length. The 4.3mm screw is also available in lengths of 38mm to 50mm (in 2mm increments) and 55mm to 65mm (in 5mm increments) and will be offered fully threaded, with a short partial 16mm thread and a long partial 32mm thread. The 4.3mm screw has a cannulation that will accept a 1.6mm guide wire.

Summary of Technologies: The Self-Countersinking Bone Screw's technological characteristics (materials, design, sizes, and indications) are similar to or identical to the predicate devices.

Non-Clinical Testing: Mechanical testing was performed to establish substantial equivalence to the predicate devices.

Clinical Testing: Clinical testing was not used to establish substantial equivalence to predicate devices.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 7 2001

Ms. Sara B. Shultz
Regulatory Specialist
Biomet Orthopedics, Inc.
P.O. Box 587
Warsaw, IN 46581-0587

Re: K013534
Trade/Device Name: Self-Countersinking Bone Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: October 22, 2001
Received: October 23, 2001

Dear Ms. Shultz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K013534

DEVICE NAME: Self-Countersinking Bone Screw

INDICATIONS FOR USE:

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- Arthrodesis of the foot, ankle, wrist, and elbow
- Small bone osteotomies
- Osteochondritis dissecans

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K013534

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter-Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)